

K961856

United States Surgical Corporation
510(k) Premarket Notification
Auto Suture* Chemosite* Tunneler**

JUL 18 1986

**SUMMARY OF INFORMATION SUPPORTING
SAFETY AND EFFECTIVENESS:**

As is evident in the submitted information on design, indications, materials and method of use, the Auto Suture* Chemosite* Tunneler** is substantially equivalent to the Cook™ Trocar Tunnelator™, the Davol® Tunneler and other currently marketed devices by United States Surgical Corporation.

- Both the Auto Suture* Chemosite* Tunneler** and the Davol® Tunneler have similar indications, namely, for use with implantable drug delivery ports and catheters and for use in the subcutaneous positioning of long-term vascular access catheters and subcutaneous ports.
- Both the Auto Suture* Chemosite* Tunneler** and the Cook™ Trocar Tunnelator™ are comprised of biosafe materials, such as stainless steel.
- Both the Auto Suture* Chemosite* Tunneler** and the Cook™ Trocar Tunnelator™ are composed of an angled stainless steel shaft.
- Both the Auto Suture* Chemosite* Tunneler** and Auto Suture* Chemosite* Implantable Drug Delivery System (K952748) currently marketed by United States Surgical Corporation are manufactured in similar facilities, using similar materials and process methods and controls.
- Both the Auto Suture* Chemosite* Tunneler** and the Auto Suture* Chemosite* Implantable Drug Delivery System (K952748) currently marketed by United States Surgical Corporation are packaged in similar facilities, with the same materials and with the same process methods and controls.
- Both the Auto Suture* Chemosite* Tunneler** and the Auto Suture* Chemosite* Implantable Drug Delivery System (K952748) currently marketed by United States Surgical Corporation are sterilized in similar facilities, with the same materials and with the same process methods and controls.

* Trademark of United States Surgical Corporation.
** Trademark name not yet determined.